DEC - 4 2003

510(k) Summary

Medisim Ltd.

UP-GRADE FOREHEAD THERMOMETER

510(k) Number K032362

Applicant's Name:

Medisim Ltd.
Airport City
2A Hayarden str.70151, Israel
Tel: 972-3 9795560
Fax: 972-3 9795541

Contact Person:

Dalia Givony
Airport City
2A Hayarden str.70151, Israel
Tel: 972-3 9795560
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dalia@medisim.co.il

Trade Name:

UP-GRADE FOREHEAD THERMOMETER

Classification Name:

Clinical Electronic Thermometer

Classification:

Clinical Electronic Thermometers are class II devices (product code 80 FLL) and are reviewed by the General Hospital Division.

Indication for Use:

The Up-Grade Forehead Thermometer is a non-sterile, reusable clinical thermometer intended for the determination of human's body temperature using the forehead as measurement site.

Predicate Devices:

The Up-Grade Forehead Thermometer is substantially equivalent in intended use, technology characteristics, and performance characteristics to the:

- UP-Grade Thermometer (Medisim LTD.) cleared under K983887
- M5T Instant Thermometer (Medisim LTD.) cleared under K012217
- Thermoteck (SAAT Ltd.) IR Forehead Thermometer model 718F cleared under K002712.
- Scanner (Exergen Co.) Cleared under K011291.

Device Description:

The over-the-counter Up-Grade Forehead Thermometer is a compact predictive clinical thermometer designed to measure human body temperature by detecting heat flow from the temporal artery, by using the heat conduction principle and prediction.

The over-the-counter Up-Grade Forehead Thermometer is designed to calculate the maximum temperature of a probe in contact with the body site, without waiting for thermal equilibrium to occur, by heat transfer data and mathematical algorithm. The temperature reading range is from 35.0°C to 42.0°C (95.5°F to 107.6°F) and the time of measurement is 6-10 seconds.

Non-Clinical and Clinical Tests Performed for Determination of Substantial Equivalence:

The ***Up-Grade Forehead Thermometer*** is an electronic thermometer complies with the following voluntary standards: ASTM E1112, IEC 60601-1 and EN 60601-1. Additionally, the safe and effective performance of the device has been non-clinically and clinically established through comparative testing with market-cleared devices.

Conclusion:

Based on the safety and performance testing and compliance with acceptable voluntary standards, we believe that the Up-Grade Forehead Thermometer is substantially equivalent to its predicate devices cited above and does not raise any new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2003

Ms. Dalia Givony
Clinical &Regulatory Manager
Medisim Limited
Airport City, 2A Hayarden Str.
ISRAEL 70151

Re: K032362
Trade/Device Name: Up-Grade Forehead Thermometer
Regulation Number: 880.2910
Regulation Name: Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: September 30, 2003
Received: September 15, 2003

Dear Ms. Givony:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K032362

Device Name: **UP-GRADE FOREHEAD THERMOMETER**

Indications for Use:

The **UP-GRADE FOREHEAD THERMOMETER** is a non-sterile, reusable clinical thermometer intended for the determination of human's body temperature using the forehead as measurement site.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over the Counter Use ✓
(Per 21 CFR 801.109)

Patricia Cucuzzella

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032362